Tumor Consortium, the New Approaches to Neuroblastoma Therapy or other pediatric oncology consortia.

(iii) At least 2 representatives of the pediatric cancer patient and patient-family community.

(iv) 1 representative of the nursing community.

(v) At least 1 statistician.

(vi) At least 1 representative of the pharmaceutical industry.

(e) PRE-CLINICAL MODELS TO EVALUATE PROMISING PEDIATRIC CANCER THERAPIES.—Section 413 of the Public Health Service Act (42 U.S.C. 285a–2) is amended by adding at the end the following:

''(c) PRE-CLINICAL MODELS TO EVALUATE PROMISING PEDIATRIC CANCER THERAPIES.—

''(1) EXPANSION AND COORDINATION OF ACTIVITIES.—The Director of the National Cancer Institute shall expand, intensify, and coordinate the activities of the Institute with respect to research on the development of preclinical models to evaluate which therapies are likely to be effective for treating pediatric cancer.

''(2) COORDINATION WITH OTHER INSTITUTES.—The Director of the Institute shall coordinate the activities under paragraph (1) with similar activities conducted by other national research institutes and agencies of the National Institutes of Health to the extent that those Institutes and agencies have responsibilities that are related to pediatric cancer.''.

(f) CLARIFICATION OF AVAILABILITY OF INVESTIGATIONAL NEW DRUGS FOR PEDIATRIC STUDY AND USE.—

(1) AMENDMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Section 505(i)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(1)) is amended—

(A) in subparagraph (B), by striking ''and'' at the end;

(B) in subparagraph (C), by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following:

''(D) the submission to the Secretary by the manufacturer or the sponsor of the investigation of a new drug of a statement of intent regarding whether the manufacturer or sponsor has plans for assessing pediatric safety and efficacy.''.

(2) AMENDMENT OF THE PUBLIC HEALTH SERVICE ACT.—Section 402(j)(3)(A) of the Public Health Service Act (42 U.S.C. 282(j)(3)(A)) is amended in the first sentence—

(A) by striking ''trial sites, and'' and inserting ''trial sites,''; and

(B) by striking ''in the trial,'' and inserting ''in the trial, and a description of whether, and through what procedure, the manufacturer or sponsor of the investigation of a new drug will respond to requests for protocol exception, with appropriate safeguards, for single-patient and expanded protocol use of the new drug, particularly in children,''.

(g) REPORT.—Not later than January 31, 2003, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs and in consultation with the Director of the National Institutes of Health, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on patient access to new therapeutic agents for pediatric cancer, including access to single patient use of new therapeutic agents.

SEC. 15. REPORT ON PEDIATRIC EXCLUSIVITY PROGRAM.

(a) IN GENERAL.—Not later than January 31, 2007, the Secretary of Health and Human Services, in consultation with the Comptroller General of the United States, shall submit to Congress a report that addresses the following issues, using publicly available data or data otherwise available to the Government that may be used and disclosed under applicable law:

(1) The effectiveness of this Act and the amendments made by this Act in ensuring that medicines used by children are tested and properly labeled, including—

(A) the number and importance of drugs for children that are being tested as a result of this legislation and the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;

(B) the number and importance of drugs for children that are not being tested for their use notwithstanding the provisions of this legislation, and possible reasons for the lack of testing; and

(C) the number of drugs for which testing is being done, exclusivity granted, and labeling changes required, including the date pediatric exclusivity is granted and the date labeling changes are made (noting whether or not labeling changes were requested by the Food and Drug Administration and what, if any, recommendation was made by the Pediatric Advisory Committee).

(2) The economic impact of this Act and the amendments made by this Act, including an estimate of—

(A) the costs to taxpayers in the form of higher expenditures by medicaid and other Government programs;

(B) increased sales for each drug during the 6-month period for which exclusivity is granted;

(C) costs to consumers and private insurers as a result of any delay in the availability of lower cost generic equivalents of drugs tested and granted exclusivity under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), and loss of revenue by the generic drug industry as a result of any such delay; and

(D) savings to taxpayers (in the form of lower expenditures by medicaid and other Government programs), private insurers, and consumers due to more appropriate and more effective use of medications in children as a result of testing and relabeling, including savings from fewer hospitalizations and fewer medical errors.

(3) The nature and type of studies in children for each drug granted exclusivity under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), including—

(A) a description of the complexity of the studies;

(B) the number of study sites necessary to obtain appropriate data;

(C) the numbers of children involved in any clinical studies; and

(D) the estimated cost of each of the studies.

(4) Any recommendations for modifications to the programs established under section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) and section 409I of the Public Health Service Act this Act (as added by section 3) that the Secretary determines to be appropriate, including a detailed rationale for each recommendation.

(5) The increased private and Government-funded pediatric research capability associated with this Act and the amendments made by this Act.

(6) The number of written requests and additional letters of recommendation that the Secretary issues.

(7) The prioritized list of off-patent drugs for which the Secretary issues written requests.

(8)(A) The efforts made by Secretary to increase the number of studies conducted in the neonate population; and

(B) the results of those efforts, including efforts made to encourage the conduct of appropriate studies in neonates by companies with products that have sufficient safety and other information to make the conduct of studies ethical and safe.

(b) TIMING.—

(1) REPORT ON METHODOLOGY.—Not later than January 31, 2004, the Secretary shall submit to Congress a report explaining the methodology that the Secretary intends to use to prepare the report under subsection (a).

(2) INTERIM REPORTS.—Before submission of a final report under subsection (a), the Secretary shall periodically make publicly available information on the matters described in paragraphs (1), (3), (6), and (7) of subsection (a).

SEC. 16. TECHNICAL AND CONFORMING AMENDMENTS.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) (as amended by sections 2(1), 5(b)(2), 9, 10, and (11)) is amended—

(1)(A) by striking ''(j)(4)(D)(ii)'' each place it appears and inserting ''(j)(5)(D)(ii)'';

(B) by striking ''(j)(4)(D)'' each place it appears and inserting ''(j)(5)(D)''; and

(C) by striking ''505(j)(4)(D)'' each place it appears and inserting ''505(j)(5)(D)'';

(2) by redesignating subsections (a), (g), (h), (i), (j), (k), (l), (m), (n), and (o) as subsections (b), (a), (g), (h), (n), (m), (i), (j), (k), and (l) respectively;

(3) by moving the subsections so as to appear in alphabetical order;

(4) in paragraphs (1), (2), and (3) of subsection (d), subsection (e), and subsection (m) (as redesignated by paragraph (2)), by striking ''subsection (a) or (c)'' and inserting ''subsection (b) or (c)''; and

(5) in subsection (g) (as redesignated by paragraph (2)), by striking ''subsection (a) or (b)'' and inserting ''subsection (b) or (c)''.

SA 1906. Mr. HATCH submitted an amendment intended to be proposed by him to the bill S. 838, to amend the Federal Food, Drug, and Cosmetic Act to improve the safety and efficacy of pharmaceuticals for children; which was ordered to lie on the table; as follows:

Amend section 10 to read as follows:

''(n)(1)(B). If the 180-day period would, but for this subsection, expire after the 6-month extension, by the period of overlap.''

''(n)(2). Under no circumstances shall application of this section result in an applicant for approval of a drug under section 505(j) being entitled to an exclusivity period that (aside from the 6-month pediatric exclusivity period) prohibits the approval of a subsequent application under 505(j) for more than 180 days.''

SA 1907. Mr. REID (for Mr. DURBIN) proposed an amendment to the concurrent resolution S. Con. Res. 74, condemning bigotry and violence against Sikh-Americans in the wake of terrorist attacks in New York City and Washington, D.C. on September 11, 2001; as follows:

Strike all after the resolving clause and insert the following:

That Congress—

(1) declares that, in the quest to identify, locate, and bring to justice the perpetrators and sponsors of the terrorist attacks on the United States on September 11, 2001, the civil rights and civil liberties of all Americans, including Sikh-Americans, should be protected;

(2) condemns bigotry and any acts of violence or discrimination against any Americans, including Sikh-Americans;

(3) calls upon local and Federal law enforcement authorities to work to prevent